

**REMARKS**

Claims 1-8, 10-13, 22, 24, and 25 are pending in this application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1-5, 7, and 10-13 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Richter (EP Patent No. 0976417A) in view of Cohen (U.S. Patent No. 5,167,239) and Middleman et al. (U.S. Patent No. 7,169,160) (hereinafter “Middleman”).

Claim 1 recites an endoluminal access system for accessing a body lumen, comprising “a guide track which, when in an operative position, extends through a body lumen to a desired location therewithin; a modular device selectively coupleable to the guide track, the modular device including a drive mechanism for engaging the guide track to move the modular device along the guide track within the body lumen; and *an anchoring module selectively coupleable to the guide track for anchoring the guide track at the desired location, the anchoring module including an anchoring module drive mechanism for engaging the guide track to move the anchoring module along the guide track to the desired location, wherein the anchoring module drive mechanism is located inside the anchoring module.*”

It is first respectfully submitted that the argument presented by the Examiner is improper since the Examiner has analogized both the guidewire body 12 of Richter and the tubular element 18 of Middleman to the “guide track” of claim 1 in order to overcome arguments previously presented by the Applicants. It is respectfully submitted that this rejection is not allowable and furthermore, that neither the guidewire body 12 nor the tubular element 18 are capable of meeting the limitations of “a guide track which...extends through a body lumen to a desired location therewithin; a modular device selectively coupled to the guide track, the modular device including a drive mechanism for engaging the guide track to move the modular device along the guide track” in combination with an “anchoring module including an anchoring

module drive mechanism for engaging the guide track to move the anchoring module along the guide track to the desired location,” as recited in claim 1. Specifically, the Examiner concedes that the guidewire body 12 of Cohen does not comprise “an anchoring module” or “an anchoring module drive mechanism,” as recited in claim 1. In an earlier response, Applicants argued that Middleman also fails to teach a guidewire capable of meeting these limitations in claim 1. (See 8/13/10 Response to Office Action). In response, the Examiner notes that “the Examiner relies on member 18 for the guide track while Applicant argues with reference to member 46 for the guide track.” (See 10/15/10 Office Action, p. 9). However, it is respectfully submitted that the cited embodiment of Middleman is actuatable only by movement of a first tubular portion relative to a second tubular portion and would find no utility with a “guide track” as recited in claim 1 or with a guide wire 12 as taught by Cohen. Specifically, Middleman is directed to an anchoring apparatus 10 comprising a first tubular element 36 housed within a second tubular element 20 so that distal movement of the first element 36 relative to the second tubular element 20 exposes anchoring members 56 provided on a distal end of the first tubular element 36. (See Middleman, col. 5, ll. 26-50; Figs. 1, 3, 4, 6-11.) It is respectfully submitted that the tubular element 20 and anchoring members 56 of Middleman are not so analogous with the guidewire 12 and inflatable balloon 14 to warrant the proposed combination. Specifically, the anchoring members 56 are positioned *within* a tubular element 20 and are slidable therewithin. It is unclear how the anchoring member 56 would be adapted to the devices of Richter or Cohen, both of which require elements disposed *over* respective guidewires. The Examiner has failed to address this flaw and rather, cites both the tubular portion 20 and guidewire 12 in support of the rejection. Still further, it is evident that the anchoring members 56,60 of Middleman are movable relative to the tubular element 20 only due to their positioning therewithin. The Examiner seeks to draw out this movable property of the anchoring members 56, 60 and apply it to the balloon 14 which is positioned *over* the guide wire 12. (See 10/15/10 Office Action, pp. 3-4, 9-10). It is respectfully submitted that such a modification is improper when it is evident that the movable properties of the anchoring members 56, 60 are directly related to their positioning within the tubular element 18. That is, it is improper to apply only a functional limitation from the Middleman device without also applying the structural limitations which impart the recited

function thereto. It is therefore respectfully submitted that neither Richter nor Cohen nor Middleman teach or suggest “an anchoring module selectively coupleable to the guide track for anchoring the guide track at the desired location, *the anchoring module including an anchoring module drive mechanism for engaging the guide track to move the anchoring module along the guide track to the desired location,*” as recited in claim 1 and that claim 1 is allowable for at least this reason.

Richter, Cohen and Middleman also fail to teach or suggest “an anchoring module drive mechanism for engaging the guide track to move the anchoring module along the guide track to the desired location, wherein the anchoring module drive mechanism is located inside the anchoring module,” as recited in claim 1. In support of the rejection, the Examiner states that both Richter and Cohen are silent with regard to an “anchoring module [movable] along the guide track,” as recited in claim 1 and seeks to overcome this deficiency by citing anchoring members 56 in Middleman. (*See* 10/15/10 Office Action, pp. 9-10). However, it is respectfully submitted that the prior art references teach away from the modification proposed by the Examiner. Cohen is directed to a balloon 14 mounted over a guidewire body 12. (*See* Cohen, col. 5, ll. 13-26; Figs. 1, 3). The balloon 14 of Cohen is mounted over a predetermined position on the guidewire body 12 and is not configured to be movable relative thereto. It is therefore evident that Cohen does not teach or suggest an “anchoring module drive mechanism,” as recited in claim 1. Rather, such a feature would serve no useful purpose in the device of Cohen and would actually be detrimental to the device of Cohen as it would prevent inflation of the balloon 14 via inflation fluid from the apertures 28 provided in the predetermined position of the guidewire 12. Cohen does not teach or suggest how or if the balloon would inflate if moved along the guidewire 12 away from the apertures 28. It is therefore evident that the Examiner’s assertion that the balloon 14 of Cohen be configured to be movable per the device of Middleman is improper and fails to address an inherent deficiency in inflation of a movable balloon 14. It is therefore respectfully submitted that the modification proposed by the Examiner is not allowable for this additional reason.

Still further, it is respectfully submitted that neither Richter nor Cohen nor Middleman teach or suggest “wherein the anchoring module drive *mechanism is located inside the anchoring module*,” as also recited in claim 1. In support of the rejection, the Examiner argues that the pushing mechanism of Middleman may be replaced with the motor drive mechanism of Richter to crawl along the guidewire. (*See* 10/15/10 Office Action, p. 3, ll. 15-21). Specifically, the Examiner concedes that only Richter teaches any drive mechanism at all and has argued a proposed modification wherein an additional drive mechanism is provided to drive the anchoring module. However, it is respectfully submitted that Richter only teaches a drive mechanism disposed over a guidewire 12 and thus provides no support for an “anchoring module drive mechanism [that] is located inside the anchoring module,” as recited in claim 1. Since Cohen is silent with respect to a drive mechanism, it is evident that Cohen fails to cure this deficiency. Middleman teaches a pushing mechanism formed as a lumen 20 located proximally of the anchoring members 56, 60 and therefore also fails to cure this deficiency. It is respectfully submitted that claim 1 is therefore allowable for at least this additional reason.

It is therefore respectfully submitted that Richter, Cohen and Middleman, taken either alone or in any combination, fail to show or suggest “an anchoring module selectively coupleable to the guide track for anchoring the guide track at the desired location, the anchoring module including an anchoring module drive mechanism for engaging the guide track *to move the anchoring module along the guide track to the desired location, wherein the anchoring module drive mechanism is located inside the anchoring module*,” as recited in claim 1 and that claim 1 is allowable for at least this reason.

Because claims 2-5, 7, 10-12 and 13 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view of Cohen and Middleman in further view of Ziegler et al. (U.S. Patent No. 6,971,990) (hereinafter “Ziegler”).

Claim 8 depends from and therefore includes all of the limitations of independent claim 1. As noted above, Richter, Cohen and Middleman, taken alone or in any combination, fail to teach or suggest the limitations of claim 1. Ziegler fails to cure these deficiencies. It is therefore respectfully submitted that claim 1 is allowable over Richter, Cohen, Middleman and Ziegler, taken alone or in any combination. Claim 8 is therefore also allowable as being dependent on an allowable base claim.

Claim 6 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view of Kindlein (U.S. Patent No. 7,229,401) (hereinafter “Kindlein”) in further view of Ziegler.

Claim 6 recites an endoluminal access system for accessing a body lumen, comprising “a modular device selectively coupleable to the guide track, the modular device including a drive mechanism for engaging the guide track to move the modular device along the guide track within the body lumen, wherein the drive mechanism includes a threaded member for engaging a contact surface of the guide track and rotating about the guide track, and wherein the threaded member includes a threaded hole.”

It is respectfully submitted that Richter, Kindlein and Ziegler fail to teach or suggest “a threaded member for engaging a contact surface of the guide track *and rotating about the guide track*,” as recited in claim 6. Specifically, claim 6 is directed to a threaded member configured and dimensioned with a contact surface that rotates *about* the guide track. It is evident that none of the cited references teach anything capable of meeting this structural limitation in claim 6. Specifically, the drive wheels of Kindlein remain stationary with respect to the needle 10. (See Kindlein, col. 8, ll. 45-60; Figs. 6A, 6B). Similarly, the motive roller 534 of Ziegler remains stationary on a lateral side of the worm gear 544 and does not rotate thereabout. (See Ziegler, col. 9, ll. 1-17; Fig. 5). The Examiner has not cited anything in any of the prior art references capable of meeting this limitation in claim 6. It is therefore respectfully submitted that claim 6 is allowable for at least this reason.

Furthermore, Richter, Kindlein and Ziegler, taken alone or in combination, also fail to teach or suggest a drive mechanism including “a threaded member for engaging a contact surface of the guide track and rotating about the guide track, and *wherein the threaded member includes a threaded hole*,” as recited in claim 6. The Examiner agrees that Richter fails to teach or suggest the aforementioned limitation in claim 6. (See 10/15/10 Office Action, p. 6). It is further respectfully submitted that Kindlein also fails to teach or suggest any element capable of meeting the aforementioned limitation. The Examiner argues that Kindlein teaches drive wheels 31, 33a-d that create a hole through which a needle is advanced. (See 10/15/10 Office Action, p. 10). However, it is respectfully submitted that a space defined between a plurality of elements in Kindlein does not meet the limitations of a “hole” which is known to those of skill in the art as “an opening into or through anything.” (See Definition, Webster’s Third New International Dictionary). The recited space in Kindlein is not configured as an opening *into* or *through* any other element. It is therefore respectfully submitted that Richter, Kindlein and Ziegler, taken alone or in combination, fail to teach or suggest “a threaded member for engaging a contact surface of the guide track and rotating about the guide track, and *wherein the threaded member includes a threaded hole*,” as recited in claim 6 and that claim 6 is in condition for allowance.

Claims 22, 24 and 25 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Richter in view of McAlister et al. (U.S. Patent Publn. No. 2002/00065523) (hereinafter “McAlister”) in further view of Cohen and Middleman.

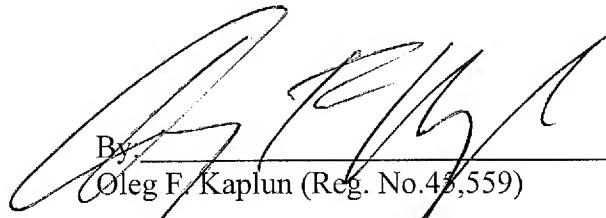
As noted above in response to the 35 U.S.C. § 103(a) rejection of claims 1-5, 7 and 10-13, Richter, Cohen and Middleman fail to teach or suggest the steps of “inserting a guide track to a desired location within the body lumen; selectively coupling an anchoring module to the guide track; actuating a motor of the anchoring module in order to advance the anchoring module along the guide track to a desired location within the bodily lumen [and] anchoring the guide track at the desired location within the body lumen via the anchoring module,” as recited in claim 22. McAlister fails to cure these deficiencies. It is therefore respectfully submitted that Richter, McAlister, Cohen and Middleman, taken alone or in any combination, fail to teach or

suggest “inserting a guide track to a desired location within the body lumen; selectively coupling an anchoring module to the guide track; actuating a motor of the anchoring module in order to advance the anchoring module along the guide track to a desired location within the bodily lumen [and] anchoring the guide track at the desired location within the body lumen via the anchoring module,” as recited in claim 22 and that claim 22 is in condition for allowance. Because claims 24 and 25 depend from and therefore include all of the limitations of independent claim 22, it is respectfully submitted that these claims are also allowable.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, and an early and favorable action on the merits is earnestly solicited.

Respectfully Submitted,

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